

## REMARKS

### I. Status of the Application

Claims 1-40 are presently pending in the application. Claims 8-26 and 36 have been withdrawn by the Examiner. Claims 6, 7, 27, 30, 34, 39 and 40 stand rejected under 35 U.S.C. § 112 second paragraph as being indefinite. Claims 1-5, 28, 32 and 37 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Hahn US 5,129,889. Claim 35 stands rejected under 35 U.S.C. § 102(b) as being anticipated by, or in the alternative, under 35 U.S.C. §103(a) as being obvious over Hahn. Claims 6-7, 30-31 and 38-40 stand rejected under 35 U.S.C. § 103(a) as being obvious over Hahn. Claim 27 stands rejected under 35 U.S.C. § 103(a) as being obvious over Hahn in view of Jackson US 2003/0134811. Claim 29 stands rejected under 35 U.S.C. § 103(a) as being obvious over Hahn in view of Noda US 6,669,711. Claims 33-34 stand rejected under 35 U.S.C. § 103(a) as being obvious over Hahn in view of Goldsmith US 5,026,378.

Claim 1 has been amended to include an elastic modulus of up to 120 MPa. Support for the language is found at page 15 lines 19-21 of the specification. Accordingly, no new matter has been added.

Applicants respectfully request reconsideration of the foregoing claims in view of the amendments and remarks.

### II. The Indefiniteness Rejections

At pages 3-5 of the present office action, the Examiner has raised several concerns about certain claim language. In response, applicants have amended the claims consistent with the Examiner's suggestions to overcome the present indefiniteness rejections. Accordingly, withdrawal of the rejections under 35 U.S.C. § 112, second paragraph is respectfully requested.

### **III. Claims 1-5, 28, 32 and 37 Are Not Anticipated By Hahn**

At page 5 of the present office action, claims 1-5, 28, 32 and 37 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Hahn US 5,129,889. At page 6 of the present office action, claim 35 stands rejected under 35 U.S.C. § 102(b) as being anticipated by, or under 35 U.S.C. §103(a) as being obvious over Hahn US 5,129,889. The Examiner believes that Hahn teaches each and every limitation of claims 1-5, 28, 32, 35 and 37. Applicants respectfully traverse the Examiner's rejection based on the amended claims now presented.

At the outset, applicants note that claims 1-5, 28, 32, 35 and 37 each require that the claimed polymer be elastic. The specification at page 5 line 28 teaches that the drains are preferably flexible and elastic. The specification at page 13 lines 20-21 further teaches that the drains are flexible, pliable and elastic. Applicants respectfully submit that the catheter of Hahn does not teach an elastic polymer. The catheters of Hahn, by their nature, are stiff and are not elastic. The stiffness is achieved by using either crystalline materials or materials having a glass transition temperature above body temperature.

However, despite the claims already distinguishing over Hahn by reciting an elastic polymer, applicants have amended the claims to recite an elastic modulus of up to 120 MPa. The materials used to make the catheter of Hahn do not have this elastic modulus. Representative materials of Hahn have the following elastic moduli.

Polydioxanone	1200-1700 MPa
Polycaprolactone	200 MPa
Polylactide	400-2800 MPa
Polyglycolide	7000-14000 MPa
Vicryl	7000-14000 MPa

PDS                    1200-1700 MPa

Maxon                3000-3400 MPa

From this review of materials, applicants assert that the catheters of Hahn do not possess the required property of being elastic or having an elasticity modulus of up to 120 MPa. Since Hahn fails to teach each and every limitation of claims 1-5, 28, 32, 35 and 37, Hahn cannot anticipate, or render obvious, those claims. Accordingly, applicants respectfully request that the rejection of the claims based on Hahn be withdrawn.

**IV. Claims 6-7, 30-31 and 38-40 Are Not Obvious Over Hahn**

At page 7 of the present office action, claims 6-7, 30-31 and 38-40 stand rejected under 35 U.S.C. § 103(a) as being obvious over Hahn. Applicants respectfully traverse the Examiner's rejection as to the amended claims now presented.

As discussed above, Hahn fails to teach or suggest an elastic polymer or a polymer having an elastic modulus of up to 120MPa. It is further submitted that Hahn fails to teach or suggest a drain. Instead, Hahn teaches a device for delivering anesthetic to an individual and not a device for removing fluid from an individual. There is no indication in Hahn that its epidural catheter can function, at least intentionally, as a drain.

As further discussed above, the nature of Hahn's catheter indicates use of rigid materials (see abstract and col. 2 lines 31-32 describing "dimensionally and structurally stable" materials) that are different from the claimed elastic materials. It is respectfully submitted that the rigid materials are required in order to use the catheter as described in Hahn, especially the steps of inserting the catheter into the spine of an individual via forcing the catheter through a needle and further allowing the catheter to remain dimensionally and structurally stable in the individual so

as to allow the uninterrupted flow of anesthetic into an individual. Detrimental changes in flow can occur upon changes of the dimension of a less rigid structure. It is respectfully submitted that elastic materials having an elastic modulus of up to 120 MPa are different from those used in the epidural catheter of Hahn. Since Hahn fails to teach all of the limitations of the amended claims now presented, the Examiner has not presented a *prima facie* case of obviousness. Accordingly, on this basis, applicants respectfully request that the rejection of the claims based on Hahn be withdrawn.

It is further respectfully submitted that one of skill would not be led in the direction of the invention, i.e. elastic polymers having an elastic modulus of up to 120 MPa, but instead would be led away from the invention given the operational requirements of the catheter of Hahn. At page 8 of the present office action, the Examiner states that “it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Hahn for the purpose of making a drain that would have the right structures for draining fluids out of a patient.” It is clear from this position that Hahn does not have the “right structure for draining fluids out of a patent” and would, accordingly, need to be modified. However, applicants respectfully submit that one of skill would need to do more than modify Hahn. One of skill would need to look for an entirely different device, and this supports the lack of obviousness of the claimed drain. There is nothing in the catheter of Hahn that would direct one of skill to look to the drain art or to envision using an elastic material as claimed, as there is no evidence that such a material would prove useful in the catheter of Hahn. In fact, only applicants’ specification provides a drain made of an elastic polymer and it is impermissible hindsight for the Examiner to use the specification as a roadmap to applicants’ invention.

Accordingly, applicants respectfully request that the rejection of the claims based on Hahn be withdrawn.

**V. Claim 27 Is Not Obvious Over Hahn and Jackson**

At page 9 of the present office action, claim 27 stands rejected under 35 U.S.C. § 103(a) as being obvious over Hahn and Jackson. Applicants respectfully traverse the Examiner's rejection as to the amended claims now presented.

For the reasons discussed above, Hahn fails to teach or suggest all of the limitations of claim 27. Jackson, which is relied upon for the teaching of anti-inflammatory agents mixed into a biodegradable polymer, fails to cure the deficiencies of Hahn. Accordingly, applicants respectfully request that the rejection of claim 27 based on Hahn and Jackson be withdrawn.

**VI. Claim 29 Is Not Obvious Over Hahn and Noda**

At page 10 of the present office action, claim 29 stands rejected under 35 U.S.C. § 103(a) as being obvious over Hahn and Noda. Applicants respectfully traverse the Examiner's rejection as to the amended claims now presented.

For the reasons discussed above, Hahn fails to teach or suggest all of the limitations of claim 29. Noda, which is relied upon for the teaching of a nasal drain, fails to cure the deficiencies of Hahn. Accordingly, applicants respectfully request that the rejection of claim 29 based on Hahn and Noda be withdrawn.

**VII. Claims 33-34 Are Not Obvious Over Hahn and Goldsmith**

At page 10 of the present office action, claims 33-34 stand rejected under 35 U.S.C. § 103(a) as being obvious over Hahn and Goldsmith. Applicants respectfully traverse the Examiner's rejection as to the amended claims now presented.

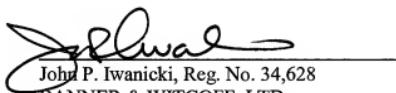
For the reasons discussed above, Hahn fails to teach or suggest all of the limitations of claims 33-34. Goldsmith, which is relied upon for the teaching of a funnel shape, fails to cure the deficiencies of Hahn. Accordingly, applicants respectfully request that the rejection of claims 33-34 based on Hahn and Goldsmith be withdrawn.

**VIII. Conclusion**

Having addressed all outstanding issues, Applicants respectfully request reconsideration and allowance of this case. To the extent the Examiner believes that it would facilitate allowance of the case, the Examiner is requested to telephone the undersigned at the number below. The Commissioner is authorized to apply any additional charges or credits to Deposit Account No. 19-0733.

Respectfully submitted,

Dated: July 6, 2009



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